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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,817	01/23/2002	Philip Christopher Buxton	P32875-1	5917

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	**PAPER NUMBER**
1615	5

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/055,817	Applicant(s) BUXTON ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Fee, Declaration, and Extension of Time, all received by the Office August 9, 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/18036 to Gaster *et al.*, in view of Remington's Pharmaceutical Sciences and the International Cosmetic Ingredient Dictionary and Handbook.

Gaster teaches Applicant's claimed compound and pharmaceutically acceptable salts thereof (claims 1-10). Gaster also teaches pharmaceutical compositions comprising the compound or salt thereof, and pharmaceutically acceptable carriers. The compositions are

usually adapted for oral, nasal, rectal, or parenteral administration, and may be in the form of tablets, capsules, ora liquid formulations, powders, granules, lozenges, reconstitutable powders, nasal sprays, suppositories, injectable and infusible solutions or suspensions (page 7, lines 27-38). Gaster teaches that the tablets and capsules are presented in a unit dosage form and contain conventional excipients, such as binders, fillers, diluents, tableting agents, lubricant, disintegrants, colorants, and others (page 8, lines 1-6). Gaster also teaches that the methods of making the compositions are traditional and known in the art (page 8, line 36).

Gaster does not specifically teach the particle size of the invention. However, Gaster teaches that the formulation can be in powder, granular, tablet, or capsule form, and that the formulations can be made by methods traditionally known in the pharmaceutical art. Furthermore, absent a clear showing to the contrary, the determination of a particular particle size is well within the skill of the ordinary worker as part of the process of normal optimization, particularly when the reference broadly teaches the use of granules, and trusts the skilled practitioner to follow conventional methods in making the described product.

Remington's Pharmaceutical Sciences, the 18th edition, is relied upon for the teaching that wet granulation is the most widely used and most general method of tablet preparation, The reference teaches that this popularity is due to the greater probability that the granulation will meet all the physical requirements for the compression of good tablets. The reference also details the steps generally understood to be included in wet granulation.

Furthermore, Gaster does not teach each of the specific excipients claimed by Applicant. However, The International Cosmetic Ingredient Dictionary and Handbook is relied upon to show that Applicant's choices for excipients are obvious selections. The reference teaches the

use of calcium phosphate as a bulking agent, and hydroxypropyl methyl cellulose as a binder. The selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to Applicant's specific selection.

For the above reasons, it is the position of the examiner that one skilled in the art would have been motivated to make a pharmaceutical composition comprising the active agent or a salt thereof disclosed by Gaster, in combination with a pharmaceutical carrier, based on the teachings of the reference. Furthermore, one would have been motivated to make the formulation using wet granulation, as that it taught as the most popular method of making tablets, and Gaster teaches to use conventional methods in making his formulations. The expected result would be a successful pharmaceutical formulation comprising the active agent taught by Gaster. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THURMAN K. PAGE, J.D.
SUPERVISORY PATENT EXAMINER